BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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Department of Health and Human Services
Division of Dockets Management
Food and Drug Administration
Electronic Submission to:
http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm

Re: Docket No. 2004S-0170 - Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Priority Topics for Research

Dear Sir or Madam:

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) authorized funding for the Agency for Healthcare Research and Quality (AHRQ) to develop an agenda for research on the comparative clinical effectiveness and appropriateness of health care items and services, including prescription drugs. The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to submit recommendations for the initial priority list.

BCBSA is a federation of 41 independent, locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage to over 88 million Americans. Our Plans have extensive experience in providing prescription drug coverage through a variety of products and delivery mechanisms designed to meet the quality and value demands of their customers. BCBSA agrees with HHS that the initial priority list should be directed toward evaluating existing evidence regarding the comparative clinical effectiveness of prescription drugs in anticipation of the Medicare prescription drug benefit.

Currently, there is a lack of published clinical studies that directly compare the effectiveness and outcomes of available drug treatments for various medical conditions. BCBSA recommends that studies be undertaken for currently used FDA-approved medications in drug therapeutic categories that contain high cost drugs and high utilization. Data from selected Blue Cross and Blue Shield Plans demonstrate that for our senior membership, the following drug therapeutic classes comprise the highest cost and utilization: (1) Cardiovascular, (2) Behavioral Health/CNS, (3) Metabolic/hormonal, (4) Gastrointestinal, and (5) Diabetes.

Recommendations

I. Studies in cardiovascular treatment should be a priority. Considerations could include: equivalency and morbidity studies comparing generic and brand statins alone and in combination with other lipid lowering drugs for the treatment of lipid disorders; and the comparison of outcomes of treatment with ACEs and ARBs for hypertension.

II. In the behavioral health area, we recommend considering effectiveness and adverse effect studies for the long term use of antidepressants, atypical antipsychotic and drugs for insomnia.

III. For diabetes, we recommend comparing the effectiveness of various insulin types or other new oral agents (e.g., glitazones) when added to a sulfonylurea/metformin regimen.

IV. COX II drugs are frequently prescribed for the treatment of pain and arthritis. Additional studies comparing COX IIs to standard NSAIDs with a focus on adverse effects are needed. In addition, NSAIDs should be studied for the potential prevention of cancer. The manufacturers of COX II drugs have studies underway for this indication. Due to the significant difference in cost between branded COX IIs and generic NSAIDs, it is important to determine if generic NSAIDs have similar effectiveness for this potential indication.

V. Biologic drug utilization and costs are expected to increase significantly over the next few years. Good long-term effectiveness and outcome studies for these new innovative products are scarce. Most published studies, typically sponsored by the manufacturer, do not compare effectiveness of new products to that of existing non-biologic treatment options or to other available biologic treatments. Consideration should be given to further studies in this area. For example, evaluating the effectiveness and optimal duration of supportive treatment for adverse effects of oncology drugs, such as anemia should be considered. Such a study should also evaluate the potential tumor stimulating effects of epogen in the treatment of anemia from chemotherapy.

BCBSA believes that AHRQ's work in comparative effectiveness research will be an important first step toward providing objective, science-based information that will better guide health care decision making. We applaud HHS and AHRQ for their work on this important initiative. If you have any questions regarding these recommendations, please contact Nan North at (202) 626-8649.

Sincerely,

Alissa Fox

Alissa Fox
Executive Director, Policy
Office of Policy and Representation